

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

ELI LILLY AND COMPANY,

Plaintiff,

vs.

VALHALLA VITALITY LLC,

Defendant.

ANSWER WITH JURY DEMAND

Case No. 2:25-cv-196

Valhalla Vitality LLC (“Valhalla”), by and through its attorneys Frier Levitt, LLC, hereby submits its Answer to the Complaint as follows:

1. Valhalla denies the allegations in paragraph 1 of the Complaint.
2. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, except to admit only that Plaintiff manufactures and sells two FDA approved drug products containing tirzepatide, MOUNJARO® and ZEPBOUND®.
3. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 3 of the Complaint, except to admit only that Plaintiff is the only company in the U.S. with FDA-approved products containing tirzepatide.
4. Valhalla denies the allegations in paragraph 4 of the Complaint, except to admit only that compounded drugs are not FDA-approved, are not reviewed by the FDA for safety and efficacy, and that paragraph 4 purports to contain a statement by the FDA. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

5. Valhalla denies the allegations in paragraph 5 of the Complaint, except to admit only that Valhalla operates an online platform in which medical providers listed compounded tirzepatide (and other services) to potential patients.

6. Valhalla denies the allegations in paragraph 6 of the Complaint.

7. Valhalla denies the allegations in paragraph 7 of the Complaint, except to admit only that it purports to contain a statement by the FDA. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

8. Valhalla denies the allegations in paragraph 8 of the Complaint, except to admit only that Plaintiff purports to bring this action as stated in the second sentence of paragraph 8.

In Response to the Section Entitled “THE PARTIES”

9. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 9 of the Complaint.

10. Valhalla admits the allegations set forth in paragraph 10 of the Complaint.

In Response to the Section Entitled “JURISDICTION AND VENUE”

11. The allegations set forth in paragraph 11 contain legal conclusions regarding subject matter jurisdiction and are not averments of fact to which a response is required. To the extent the Court deems this paragraph an averment of fact, Valhalla denies it.

12. The allegations set forth in paragraph 12 contain legal conclusions regarding personal jurisdiction and are not averments of fact to which a response is required. With respect to the remaining allegations in this paragraph, Valhalla denies them, except to admit only that Valhalla’s principal place of business is located in this District.

13. Valhalla denies the allegations in paragraph 13 of the Complaint, except to admit only that Valhalla’s principal place of business is in this District.

14. Valhalla denies the allegations in paragraph 14 of the Complaint, except to admit only that Valhalla operates an online platform in which medical providers list services to potential patients.

15. Valhalla denies the allegations in paragraph 15 of the Complaint.

16. Valhalla denies the allegations in paragraph 16 of the Complaint, except to admit only that Valhalla's principal place of business is located in this District.

17. The allegations set forth in paragraph 17 contain legal conclusions regarding venue and are not averments of fact to which a response is required. To the extent the Court deems this paragraph an averment of fact, Valhalla denies it.

In Response to the Section Entitled "FACTUAL ALLEGATIONS"¹

18. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 18 of the Complaint.

19. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 19 of the Complaint.

20. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 20 of the Complaint.

21. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 21 of the Complaint, except to admit only that Plaintiff manufactures and sells FDA approved products containing tirzepatide under the trademarks "Mounjaro" and "Zepbound."

22. Valhalla admits the allegations set forth in paragraph 22 of the Complaint.

¹ This Section contains subheadings that are not factual averments; however, to the extent the Court deems otherwise, Valhalla denies each and every subheading.

23. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 23 of the Complaint, except to admit only that it purports to contain statements by the FDA. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

24. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 24 of the Complaint.

25. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 25 of the Complaint.

26. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint.

27. Valhalla admits the allegations set forth in paragraph 27 of the Complaint.

28. Valhalla denies the allegations in paragraph 28, except to admit only that it contains a basic definition of compounding and purports to contain statements by the FDA. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

29. Valhalla denies the allegations set forth in paragraph 29 of the Complaint, except to admit only that there are many benefits and reasons for compounding and one such benefit and clinical indication is to compound a drug without an allergen.

30. Valhalla denies the allegations in paragraph 30 of the Complaint, except to admit only that compounded drugs are not FDA-approved, are not reviewed by the FDA for safety and efficacy, and that paragraph 30 purports to contain a statement by the FDA. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

31. Valhalla denies the allegations in paragraph 31, except to admit only that it purports to contain statements by the FDA. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

32. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 32 of the Complaint. The warning letter cited in the footnote is a document which is unrelated to Valhalla and which speaks for itself.

33. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 33 of the Complaint.

34. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 34 of the Complaint.

35. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 35 of the Complaint, except to admit only that it purports to contain statements by the FDA. The safety incidents referred to in the paragraph are unrelated to Valhalla.

36. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 36 of the Complaint, except to admit only that it purports to contain to contain statements by the FDA and data published by the FDA unrelated to Valhalla. Valhalla respectfully refers the Court to the citations in the footnotes for the truth of the contents therein.

37. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 37 of the Complaint.

38. Valhalla denies the allegations set forth in paragraph 38 of the Complaint, except to admit only that Valhalla operates an online platform in which medical providers listed compounded tirzepatide (and other services) to potential patients.

39. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 39 of the Complaint, except to admit only that it purports to contain statements by the FDA and other entities. Valhalla respectfully refers the Court to the websites cited for the truth of the contents therein.

40. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 40 of the Complaint, except to admit only that it purports to contain a statement by the Obesity Medicine Association. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

41. Valhalla denies knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 41 of the Complaint, except to admit only that it purports to contain statements by the Australian Minister for Health. Valhalla respectfully refers the Court to the website cited for the truth of the contents therein.

42. Valhalla denies the allegations set forth in paragraph 42 of the Complaint.

43. Valhalla denies the allegations set forth in paragraph 43 of the Complaint, except to admit only that Valhalla operates an online platform in which medical providers listed compounded tirzepatide (and other services) to potential patients.

44. Valhalla denies the allegations set forth in paragraph 44 of the Complaint.

45. Valhalla denies the allegations set forth in paragraph 45 of the Complaint.

46. Valhalla denies the allegations set forth in paragraph 46 of the Complaint, except to admit only that Valhalla operates an online platform in which medical providers listed compounded tirzepatide (and other services) to potential patients.

47. Valhalla denies the allegations set forth in paragraph 47 of the Complaint, and denies knowledge or information sufficient to form a belief as to the truth of the allegations concerning patient reports.

48. Valhalla denies the allegations set forth in paragraph 48 of the Complaint.

49. Valhalla denies the allegations set forth in paragraph 49 of the Complaint.

50. Valhalla denies the allegations set forth in paragraph 50 of the Complaint.

51. Valhalla denies the allegations set forth in paragraph 51 of the Complaint.

52. Valhalla denies the allegations set forth in paragraph 52 of the Complaint.

53. Valhalla denies the allegations set forth in paragraph 53 of the Complaint.

54. Valhalla denies the allegations set forth in paragraph 54 of the Complaint.

55. Valhalla denies the allegations set forth in paragraph 55 of the Complaint, except to admit only that compounded drugs are not reviewed by the FDA for safety and efficacy.

56. Valhalla denies the allegations set forth in paragraph 56 of the Complaint.

57. Valhalla denies the allegations set forth in paragraph 57 of the Complaint.

58. Valhalla denies the allegations set forth in paragraph 58 of the Complaint.

59. Valhalla denies the allegations set forth in paragraph 59 of the Complaint.

In Response to the FIRST CAUSE OF ACTION

60. Valhalla realleges and reincorporates by reference each and every response above as if fully set forth herein.

61. Valhalla denies the allegations in paragraph 61 of the Complaint.

62. Valhalla denies the allegations in paragraph 62 of the Complaint.
63. Valhalla denies the allegations in paragraph 63 of the Complaint
64. Valhalla denies the allegations in paragraph 64 of the Complaint.
65. Valhalla denies the allegations in paragraph 65 of the Complaint.
66. Valhalla denies the allegations in paragraph 66 of the Complaint.
67. Valhalla denies the allegations in paragraph 67 of the Complaint.

In Response to the SECOND CAUSE OF ACTION

68. Valhalla realleges and reincorporates by reference each and every response above as if fully set forth herein.
69. Valhalla states that the allegations in paragraph 69 constitute legal conclusions to which no response is required. To the extent this paragraph is deemed to contain averments of fact, Valhalla denies them. Valhalla respectfully refers the Court to the statute set forth therein for the truth of its contents.

70. Valhalla denies the allegations in paragraph 70 of the Complaint.
71. Valhalla denies the allegations in paragraph 71 of the Complaint.
72. Valhalla denies the allegations in paragraph 72 of the Complaint.
73. Valhalla denies the allegations in paragraph 73 of the Complaint.
74. Valhalla denies the allegations in paragraph 74 of the Complaint.

In Response to the THIRD CAUSE OF ACTION

75. Valhalla realleges and reincorporates by reference each and every response above as if fully set forth herein.
76. Valhalla states that the allegations in paragraph 76 constitute legal conclusions to which no response is required. To the extent this paragraph is deemed to contain averments of fact,

Valhalla denies them. Valhalla respectfully refers the Court to the statute set forth therein for the truth of its contents.

77. Valhalla denies the allegations in paragraph 77 of the Complaint.
78. Valhalla denies the allegations in paragraph 78 of the Complaint.
79. Valhalla denies the allegations in paragraph 79 of the Complaint.
80. Valhalla denies the allegations in paragraph 80 of the Complaint.

In Response to the Section Entitled “PRAYER FOR RELIEF”

81. The allegations set forth in the WHEREFORE paragraph and its subset requests for relief (numbered 1 through 9) are not averments of fact to which a response is required. To the extent the Court deems this paragraph an averment of fact, Valhalla denies it.

WHEREFORE, Valhalla demands judgment dismissing Plaintiff's Complaint, together with costs and disbursements of this action, attorney's fees, and such other and further relief as this Court deems just and proper.

DEFENSES

FIRST AFFIRMATIVE DEFENSE

Plaintiff fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff's claims may be barred or limited under the fair use doctrine.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's claims may be barred or limited under the doctrine of puffery.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff's claim for declaratory and/or injunctive relief are moot.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's claims may be barred or limited to the extent Valhalla is an innocent violator.

SIXTH AFFIRMATIVE DEFENSE

Plaintiff is not entitled to declaratory and/or injunctive relief because it cannot demonstrate likelihood of future injury.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred because Plaintiff cannot establish Article III standing to bring suit.

EIGHTH AFFIRMATIVE DEFENSE

Valhalla has not and is not engaging in any unfair and deceptive practice.

NINTH AFFIRMATIVE DEFENSE

Valhalla has not and is not engaging in any false or misleading advertising.

TENTH AFFIRMATIVE DEFENSE

Plaintiff's alleged injuries or damages, if any, were caused, in whole or in part, by the acts and omissions of third parties over whom Valhalla had no authority or control.

ELEVENTH AFFIRMATIVE DEFENSE

Valhalla's conduct did not deceive consumers nor was it likely to confuse consumers.

TWELFTH AFFIRMATIVE DEFENSE

Lilly's claims would result in a disruption of patient care and potentially patient harm.

THIRTEENTH AFFIRMATIVE DEFENSE

Lilly's claims seek to curtail patient medical services offered by medical providers and Valhalla does not control the medical decisions and services offered by providers.

FOURTEENTH AFFIRMATIVE DEFENSE

Valhalla reserves the right to interpose each and every such other separate defense that its continuing investigation and discovery may reveal and require.

Valhalla demands a trial by jury.

Dated: April 17, 2025

Respectfully Submitted,

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